

REMARKS

Claims 1-19 are pending in the present Application. No claims have been canceled, amended, or added, leaving Claims 1-19 for consideration upon entry of the present Amendment.

Reconsideration and allowance of the claims are respectfully requested in view of the following remarks.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1 – 19 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over U.S. Patent No. 4,775,585 to Hagiwara, et al in view of U.S. Patent No. 5,939,153 to Valyi, and further in view of U.S. Patent No. 5,064,599 to Ando, et al. Applicants respectfully traverse this rejection.

The present invention is directed to a method of making a shaped article, comprising thermoforming an article comprising an exterior surface comprising an inorganic biocidal agent and a first thermoplastic resin to form the shaped article, wherein the shaped article has improved biocidal activity compared to the unshaped article.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a *prima facie* case of obviousness, i.e., that all elements of the invention are disclosed in the prior art; that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references; and that the proposed modification of the prior art had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

Hagiwara is directed to a polymer article containing zeolite particles. (See Abstract). The polymer article is produced, for example, by admixing bactericidal metal ion-containing zeolite particles with an organic polymer prior to molding, or by mixing a molded organic polymer containing a zeolite with a metal ion salt to form a metal ion-containing zeolite *in situ*. The Examples disclose molding the zeolite-containing polymer into fibers and yarns by a process

of melting, spinning, and drawing. (Col. 13, ll. 23-25). Example 1 discloses that each knitted fabric was washed 50 times and then subjected to an evaluation of an antibacterial effect. (Col. 13, ll. 28-33). Hagiwara fails to disclose thermoforming the molded article.

Valyi is directed to lined beverage containers. Valyi discloses a process for forming a multilayered plastic article and multilayered plastic preform and container, wherein a polyepoxide or a liquid crystal polymer in the liquid form is applied to a substrate in a thickness which varies over the extent of the substrate to form a multilayered substrate, forming a tubular liner from said multilayered substrate, and coating the tubular liner with an outer layer. (Abstract). The multilayer structure may be thermoformed. The polyepoxides, especially the epoxy-amine thermosetting resins, are favored because the polyepoxides do not have to be shielded from beverage contact in a beverage container. (Col. 3, ll. 9-20).

Ando is directed to conjugated fibers comprising a low-melting point component and a high-melting point component, wherein the low-melting component comprises zeolite particles. (See Abstract). Upon heating, the low-melting component spreads to increase the surface area and cause more zeolite particles to be exposed, which yields higher antibacterial activity in a fiber article produced from the conjugated fibers. (Abstract; Col. 8, ll.31-33). Ando fails to disclose thermoforming the molded article.

In making the rejection, the Examiner has stated that

the motivation to combine the teachings of Hagiwara et al., Valyi, and Ando [is] not based on their composition. Instead, the motivation to combine their teachings is that Hagiwara et al. clearly disclose that the disclosed process is suitable for making containers. Since plastic containers are typically prepared by a thermoforming process as indicated in Valyi, motivated by the expectation of success of preparing a container containing inorganic biocidal agent, it would have been obvious to one of ordinary skill in the art to recognize the value of thermoforming a process of choice [sic] for making a container.

(Office Action dated April 26, 2006, page 3, emphasis in original)

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. The present invention is directed to a shaped article, wherein the shaped article has improved biocidal activity compared to the unshaped article. Thermoforming comprises simultaneously heating and forming the article or multi-layer article, e.g., an extruded sheet, into the desired shape such as in a mold. Applicants have discovered that, unexpectedly, an article that is thermoformed to form a shaped article has superior biocidal activity over an article that is

not thermoformed. As shown in Example 1 and Table 1 of the present application, thermoforming a biocidal article improves the silver release and thus the biocidal activity of the article. (¶ [0115]). The middle of the thermoformed article had a silver release of 24 and 20 ppb, respectively, which is about 3-fold greater than the article that was not thermoformed, which had a silver release of 7.4 ppb.

Applicants reiterate their position that one of ordinary skill in the art would not be motivated to combine the references in the manner proposed by the Examiner. Hagiwara teaches polymers containing zeolites, but fails to teach thermoforming to improve biocidal metal release.

The Examiner relies on Ando for teaching that heating improves the exposure of zeolite on an article surface. The teaching of Ando, however, is limited to compositions that contain a low-melting component and a high-melting component. Ando teaches that for fibrous compositions with a low-melting point component and a high-melting point component, upon heating, the low melting point component of the resins spreads to cause more zeolite particles to be exposed on the surface. Example 1 disclose heating the fibrous article containing a low-melting component and a high-melting component at 150° C for one minute using an oven with a hot air circulation to melt the low-melting component. The low-melting component spreads and zeolite particles were seen on the surface. (Col. 9, ll. 42-49). Ando, therefore, discloses heating sufficient to melt only the low-melting component.

The present invention is directed to thermoforming, not simply heating:

Thermoforming comprises simultaneously heating and forming the article or multi-layer article, e.g., an extruded sheet, into the desired shape such as in a mold. Either vacuum or pressure against the mold may be used to form the article or multi-layer article.

(¶ [0082]) Ando fails to disclose thermoforming, or simultaneously using heat and pressure to form an article.

As is known to those of skill in the art, thermoforming involves heating an article above its core temperature. The heating regimes disclosed by Ando would fail to achieve the core temperatures required for thermoforming. Because the low-melting point component (polyethylene) of Ando has a relatively high specific heat (0.55 at 20° C and 0.7 at 120° C) and would therefore require a relatively high amount of heat energy to increase its core temperature to the thermoforming temperature. As one of ordinary skill in the art would understand,

convection heating, such as in a recirculating hot air oven, is a relatively slow method of heat transfer. Therefore the 1 to 2 minute heating regime disclosed by Ando would be insufficient to heat the core to a thermoforming temperature for the low-melting point component, let alone the high melting point component. Ando therefore fails to teach or suggest thermoforming and thus cannot teach the advantages of thermoforming as disclosed in the present application compared to the simple heating disclosed in Ando.

In order to find a reference for thermoforming, the Examiner combines the brief reference in Hagiwara to a container with a portion of Valyi, which is directed to a gas barrier liner for the inside wall of a beverage container. Applicants submit that one of ordinary skill in the art would not be motivated to combine references primarily directed to biocidal fibrous articles with a reference directed to a beverage container, and that there is no expectation of success for the use of the thermosetting technique of Valyi in the compositions of Hagiwara. Applicants also submit that Valyi expressly discloses that the useful materials for the liner are limited only to polyepoxides, preferably epoxy-amine thermosetting resins. (Valyi, Col. 3, ll. 9-20). In contrast, Hagiwara fails to disclose polyepoxides. One of ordinary skill in the art would not be motivated to modify a reference that teaches a variety of thermoplastic polymers with a thermoforming technique that is taught to be useful for a polymer that is not taught therein. In addition, one of ordinary skill in the art would be aware of the limitations of shaping a thermosetting polymer by thermoforming since a thermosetting polymer, such as the polyepoxides of Valyi, would not be as flowable as thermoplastic polymers.

Applicants further submit that Valyi teaches that both thermoforming and blow-molding yield similar results and either process can be used to shape an article depending on whether the original form is a sheet for thermoforming or a tube for blow-molding. (Col. 4, ll. 6-8). Therefore, upon reading Valyi, one of ordinary skill in the art would not be motivated to select thermoforming as compared to other methods of shaping an article. While one might try thermoforming an article such as that disclosed in Hagiwara, this is not the standard for patentability. A finding of "obvious to try" does not provide the proper showing for an obviousness determination. The requirement for a determination of obviousness is that "both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure" (emphasis added). *In re Dow Chem.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531

(Fed. Cir. 1988). An Examiner, then, cannot base a determination of obviousness on what the skilled person in the art might try or find obvious to try. Rather, the proper test requires determining what the prior art would have led the skilled person to do.

Finally, Applicants dispute that Valyi provides the motivation to use a thermoforming process to prepare a container containing an inorganic biocidal agent because Valyi fails to teach or suggest that its liner has biocidal activity or that thermoforming improves the biocidal activity of its liner.

“It is impermissible to use the claimed invention as an instruction manual or ‘template’ to piece together the teachings of the prior art so that the claimed invention is rendered obvious.”

In re Fritch 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). Applicants maintain that the Examiner has used an improper standard in arriving at the rejection of the above claims under section 103, based on improper hindsight, which fails to consider the totality of applicant’s invention and to the totality of the cited references. More specifically, the Examiner has assembled elements from disparate references with motivation gleaned only from hindsight from Applicants’ own disclosure to allegedly arrive at Applicants’ invention. In doing so, the Examiner has failed to consider the teachings of the references or Applicants’ invention as a whole in contravention of section 103, including the disclosures of the references, which teach away from Applicant’s invention.

In order to make the combination proposed by the Examiner, one would first have to combine Hagiwara and Ando, ignore the specific teaching in Ando directed to combinations of low-melting and high-melting polymer, and generalize their teaching to heating of any zeolite-containing polymers. Ando does not teach thermoforming. Then, in order to find a heating technique, one would have to focus on Hagiwara’s passing reference to a container, ignore the list of useful polymers in Hagiwara, look to Valyi, which discloses containers made from completely different polymers, and select only the teaching of thermoforming to apply to the polymers of Hagiwara. There is no teaching in Valyi that thermoforming can or should be applied to the polymers of Hagiwara, let alone polymers containing zeolites. One of skill in the art would not be motivated to make the combination suggested by the Examiner, and there certainly would be no expectation of success for the combination. Applicants respectfully submit

that Examiner has used Applicants' own disclosure as an instruction manual to piece together the teachings of the prior art.

For at least these reasons, the combined prior art teachings fail to provide a reasonable expectation of success by combining the references in the manner suggested by the Examiner. At best, this is only an "obvious to try" standard, which is not the proper standard for determining obviousness. Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner has further stated that "in view of the substantially identical composition disclosed in Hagiwara et al. and the composition as claimed," he has "a reasonable basis to believe that the claimed 'shaped article has improved biocidal activity compared to the unshaped article' is inherently possessed in Hagiwara et al." (Office Action dated April 26, 2006, page 3). To demonstrate the allegedly inherent improved biocidal activity in Hagiwara, the Examiner has stated that Ando clearly indicates that upon heating, the low melting point component of the resins spreads to cause more zeolite particles to be exposed, which yields higher antibacterial activity. Applicants submit that Ando's disclosure of heating of a low-melting point component is irrelevant as to what is inherent in the unshaped and unmelted compositions of Hagiwara.

In order to support an anticipation rejection based on inherency, an Examiner must provide factual and technical grounds establishing that the inherent feature necessarily flows from the teachings of the prior art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981) (holding that inherency must flow as a necessary conclusion from the prior art, not simply a possible one). Applicants respectfully submit that the prior art articles were not thermoformed and therefore the improved biocidal activity is not inherent in, i.e., it does not necessarily flow from, the teachings of Hagiwara. As described in Example 1 and Table 1 of the present application, a thermoformed article had silver release properties that were greater than an article that was not thermoformed. (¶ [0115]). An article that was not thermoformed therefore demonstrably does not inherently possess the biocidal metal release properties of a thermoformed article. In addition, the Examiner appears to state that if the prior art were modified to read upon the presently claimed invention, the prior art so modified would inherently possess the claimed properties of the present invention. This is an improper application of inherency.

It is further respectfully submitted that the Examiner has inappropriately used the doctrine of inherency in putting forth a rejection under 35 U.S.C. §103 (a). “The theory of inherency is normally reserved for rejections under 35 U.S.C. § 102.” *In re Grasseli*, 318 U.S.P.Q. 303 (Fed. Cir. 1983). Withdrawal of the rejection of obviousness under inherency is respectfully requested.

Even where a *prima facie* case of obviousness exists, obviousness may be rebutted by a showing of “unexpected results,” i.e., comparative test data showing that the claimed invention possesses unexpectedly improved properties, or properties that the prior art does not have. *In re Dillon*, 919 F.2d 688, 692-93, 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990) (emphasis added). The results must be of both statistical and practical significance. *Ex parte C*, 27 U.S.P.Q.2d 1492, 1497 (Bd. Pat. App. & Int. 1993).

Objective evidence or secondary considerations such as unexpected results are relevant to the issue of obviousness and must be considered in every case in which they are present. MPEP § 2141(III). Examiners must consider comparative data in the specification, which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. *In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986); MPEP § 716.01(a). Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art, which is commensurate in scope with the claims. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980); MPEP § 716.02(b) - § 716.02(e).

Applicants respectfully submit that the Examiner has failed to consider the comparative data in the specification that demonstrate the unexpected results obtained by the present composition. Instead the Examiner has made a conclusory statement that the unexpected results are “actually expected, especially to one of specially [sic] skill in the art.” (Office Action dated April 26, 2006, page 4)

As shown in Example 1 and Table 1, thermoforming results in a shaped biocidal article with about a 3-fold improvement in biocidal metal (e.g., silver) ion release in the middle of the article over a biocidal article which is not thermoformed. The thermoformed article provides improved biocidal metal ion release and therefore improved biocidal activity. The biocidal activity is evidenced specifically in Table 3 where the biocidal efficacy improved dramatically with the amount of silver release. The Examiner does not dispute the fact that the shaped article has improved biocidal activity compared to the unshaped article. Applicants respectfully submit

that the Examiner has completely failed to apply the *Graham* factors in the obviousness inquiry as required and failed to weigh objective evidence of nonobviousness. The Examiner has further compounded this error by applying a facially incorrect standard of one of special skill in the art. Applicants respectfully submit that the unexpected results disclosed in Example 1 would successfully rebut a *prima facie* case of obviousness, if it existed. Reconsideration and withdrawal of this rejection are respectfully requested.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and withdrawal of the rejection and allowance of the case are respectfully requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 50-3621.

Respectfully submitted,

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